

VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Ms. Sheila Bruschi
 Regulatory Affairs Associate
 NuVasive, Incorporated
 7475 Lusk Blvd.
 San Diego, California 92121
 Telephone: (858) 320-4515
 Fax: (858) 320-4615

OCT - 6 2009**B. Device Name**

Trade or Proprietary Name:	<i>NuVasive SpheRx II -Pedicle Screw System</i>
Common or Usual Name:	Pedicle Screw System
Classification Name:	Spinal Pedicle Screw Spinal System, Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation orthosis.
Device Class:	Class III
Classification:	§888.3050, §888.3060, §888.3070
Product Code:	NKB, KWP, MNI, MNH, KWQ

C. Predicate Devices

The subject *SpheRx II -Pedicle Screw System* is substantially equivalent to the *SpheRx II System* (K061778 & K091502) currently distributed commercially in the U.S. by NuVasive.

D. Device Description

The *NuVasive SpheRx II -Pedicle Screw System* consists of a variety of polyaxial screws, uni-planar screws, rods, locking nuts, and transverse connectors. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient.

E. Intended Use

When used as a pedicle screw fixation system, the NuVasive SpheRx Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The NuVasive SpheRx Spinal System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the NuVasive SpheRx Spinal System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Spinal stenosis
3. Spondylolisthesis
4. Spinal deformities
5. Fracture
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

F. Comparison to Predicate Devices

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests

(Not Applicable).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Nuvasive, Inc.
% Ms. Sheila Brushi
Regulatory Affairs Associate
7475 Lusk Boulevard
San Diego, California 92121

Re: K092287

Trade/Device Name: SpheRx® II – Pedicle Screw System

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: III

Product Code: NKB, KWP, MNI, MNH, KWQ

Dated: September 4, 2009

Received: September 8, 2009

QCT - 6 2009

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SpheRx[®] II -- Pedicle Screw System

Indications For Use:

When used as a pedicle screw fixation system, the NuVasive SpheRx Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

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7. Tumor resection and/or
8. Failed previous fusion


Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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